DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2006

Sonosite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K053069
Trade Name: MicroMaxx High-Resolution Ultrasound System (C3 Series)
Regulation Number: 21 CFR 892.1550; 892.1560; 892.1570
Regulation Name: Ultrasonic Pulsed Doppler Imaging System; Ultrasonic Pulsed Echo Imaging System; Diagnostic Ultrasonic Transducer
Regulatory Class: II
Product Code: IYN; IYO; ITX
Dated: October 29, 2005
Received: November 1, 2005

Dear Mr. Job:

This letter corrects our substantially equivalent letter of November 16, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite MicroMaxx High-Resolution Ultrasound System (C3 Series), as described in your premarket notification:

Transducer Model Number

D2/2 2.0 MHz Dual Element Circular Array; C60e/5-2 5.0-2.0 MHz Curved Array; HFL38/13-6 13.0-6.0 MHz Linear Array; SLA/13-6 13.0-6.0 MHz Linear Array; LAP/12-5 12.0-5.0 MHz Linear Array Laparoscopic; L38e/10-5 10.0-5.0 MHz Linear Array; TEE/8-3 8.0-3.0 MHz Trans-esophageal Echocardiography; SLT/10-5 10.0-5.0 MHz Linear Array; P10/8-4 8.0-4.0 MHz Phased Array; P17/5-1 5.0-1.0 MHz Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Table 4.3- 1 Diagnostic Ultrasound Indications for Use Form – C3 System

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	N/A
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal Imaging	Laparoscopic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
& Other	Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
Cardiac	Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
	Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures, and picture archiving, communications and storage functionality were all previously cleared in K030949. An expanded intended use for imaging guidance for peripheral nerve block procedures was previously cleared in K033367. Includes imaging of spinal cord to provide guidance for central nerve block procedures.

Note 2: PW Doppler includes PW Tissue Doppler Imaging (TDI).

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053069

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form - D2/2 Transducer

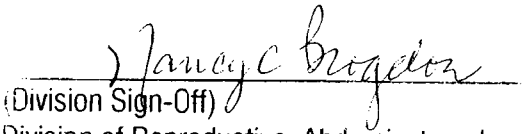
System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	**D2/2 2.0 MHz Dual Element Circular Array**
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult				P			
Cardiac	Cardiac Pediatric				P			
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note 1: All items marked "P" were previously cleared in 510(k) K043559.

Prescription Use (Per 21 CFR 801.109)



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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form - C60e/5-2 Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	C60e/5-2 5.0-2.0 MHz Curved Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles, prostate)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in 510(k) K030949. Includes imaging of spinal cord to provide guidance for central nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053069

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Table 4.3- 8 Diagnostic Ultrasound Indications for Use Form - HFL38/13-6 Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	**HFL38/13-6 13.0-6.0 MHz Linear Array Transducer**
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and an imaging guidance for peripheral nerve block procedures. All items marked "P" were previously cleared in 510(k) K043559. **Includes imaging of spinal cord to provide guidance for central nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

Table 4.3- 4 Diagnostic Ultrasound Indications for Use Form – SLA/13-6 Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	SLA/13-6 13.0-6.0 MHz Linear Array Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode.

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

Table 4.3- 13 Diagnostic Ultrasound Indications for Use Form – LAP/12-5 Laparoscopic Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	**LAP/12-5 12.0-5.0 MHz Linear Array Laparoscopic Transducer**
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. All items marked "P" were previously cleared in 510(k) K043559.

Prescription Use (Per 21 CFR 801.109)

Janet C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K053069

Table 4.3- 5 Diagnostic Ultrasound Indications for Use Form - L38e/10-5 Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	L38e/10-5 10.0-5.0 MHz Linear Array Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. **Includes imaging of spinal cord to provide guidance for central nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(K) Number K053069

Table 4.3- 6 Diagnostic Ultrasound Indications for Use Form – TEE/8-3 Trans-Esophageal Echocardiography Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 series)
Transducer:	TEE/8-3 8.0-3.0 MHz Trans-esophageal Echocardiography Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode.

Note 2: PW Doppler includes PW Tissue Doppler Imaging (TDI).

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

Table 4.3- 18 Diagnostic Ultrasound Indications for Use Form – SLT/10-5 Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 Series)
Transducer:	**SLT/10-5 10.0-5.0 MHz Linear Array**
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. All items marked "P" were previously cleared in 510(k) K043559.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

Table 4.3-7 Diagnostic Ultrasound Indications for Use Form – P10/8-4 Phased Array Transducer Intended Use Form

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 series)
Transducer:	P10/8-4 8.0-4.0 MHz Phased Array Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Intra-operative (Neuro.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal Imaging & Other	Laparoscopic							
	Pediatric	P	P	P		P	B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
	Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. This submission includes Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Note 2: PW Doppler includes PW Tissue Doppler Imaging (TDI).

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

Indications for Use

Table 4.3- 8 Diagnostic Ultrasound Indications for Use Form – P17/5-1 Phased Array Transducer

System:	MicroMaxx™ High-Resolution Ultrasound System (C3 series)
Transducer:	P17/5-1 5.0-1.0 MHz Phased Array Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic							
	Pediatric	P	P	P		P	B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
Cardiac	Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1, 2
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, Tissue Doppler Imaging and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Color Doppler can be combined with any imaging mode. This submission includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Note 2: PW Doppler includes PW Tissue Doppler Imaging (TDI).

Prescription Use (Per 21 CFR 801.109)

Indications for Use

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053069

NOV 1 6 2005 K053069

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904 USA

Telephone:1.425.951.1200
Facsimile:1.425.951.1201
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510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official:	Daina L. Graham Vice President, Regulatory Affairs and Quality Assurance
E-mail:	Daina.Graham@sonosite.com
Telephone:	(425) 951-1275
Facsimile:	(425) 951-1201
Date prepared:	October 20, 2005

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

MicroMaxx™ High-Resolution Ultrasound System (C3 Series) *(subject to change)*

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Picture Archiving And Communications System	892.2050	90-LLZ

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the SonoSite MicroMaxx™ High-Resolution Ultrasound System (C3 Series) (K043559), and the Philips Medical Systems (formerly Advanced Technology Laboratories) HDI® 5000 Ultrasound System (K034003 and K011224).

4) Device Description:

The MicroMaxx™ High-Resolution Ultrasound System (C3 Series) is a full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data in 2D, M-Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler, and Velocity Color Doppler or in a combination of these modes.

The System has an electrocardiography (ECG) display feature and supports a 3-lead ECG cable assembly to collect data for M-mode and Doppler measurements. The System provides measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The System has a PW and CW Doppler audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities.

The system includes the ability to measure the intima-media thickness (IMT) of the carotid artery using digital ultrasound images. The IMT measurement of the carotid artery may be used adjunctively with other medical data obtained by a physician to help assess the cardiovascular health of a patient.

The system includes Digital Imaging and Communications (DICOM) capabilities as well as general computer communication capabilities to provide the acceptance, transfer, display, storage, and digital processing of ultrasound images and loops. Security support is also provided to facilitate HIPAA compliance.

The MicroMaxx™ High-Resolution Ultrasound System (C3 Series) is designed to accept curved or linear transducers of the types and frequency listed in the table below. All actions affecting the performance of the transducer are activated from the main system control panel.

Frequency Range:	**2.0 - 12.0 MHz**
Transducer Types:	Linear array Curved array Intracavitary array Phased array Static probes

The MicroMaxx™ High-Resolution Ultrasound System (C3 Series) is designed to comply with the standards listed below.

FDA Recognized Consensus Standards

Reference No.	Title
AAMI/ANSI/ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)
AIUM	AIUM Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (1994)
ANSI/AAMI EC53	ECG Cables and Electrodes except for sections 4.4 and 4.5.9 (1995)
EN 980 A1	Graphical symbols for use in the labeling of medical devices (2003)
IEC 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988
IEC 60601-1/A1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A1:1991

Reference No.	Title
IEC 60601-1/A2	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A2:1995 + corrigendum June 1995
IEC 60601-1-1	Medical electrical equipment. Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems – IEC 601-1-1:2000
IEC 60601-1-2	Medical electrical equipment – Part 1: General requirements for safety; 2. collateral standard: electromagnetic compatibility; requirements and tests - IEC 60601-1-2:200
IEC 60601-1-4	Medical electrical equipment – Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems - IEC 60601-1-4:1996 Amendment A1
IEC 60601-2-25	Medical Electrical Equipment–Part 2. Particular Requirements for Safety–Section 25. Specification for Electrocardiographs. (1999
IEC 60601-2-37	Medical Electrical Equipment – Part 2-37; Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (2001)
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine

Miscellaneous Design Standards

Reference No.	Title
ASTM D5276-98	Standard Test Methods for Drop Test of Loaded Containers by Free Fall (1998)
ASTM D999-96	Standard Methods for Vibration Testing of Shipping Containers (1996)
CISPR 11	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Electromagnetic Disturbance Characteristics – Limits and Methods of Measurement (2003)
EN 60529	Degrees of protection provided by enclosures (IP Code) (1991
JIS T 0601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety (Japan) (1999)
JIS T 1507	Electronic Linear Scanning Ultrasonic Diagnostic Equipment (Japan) (1989)
JIS-T-601-1	Japanese Standards for Medical Electrical Equipment
RTCA/DO160D	Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B (1997)
UL 60601-1	Underwriters Laboratories, Medical Electrical Equipment-Part 1: General Requirements for Safety (2003)
UL 94	Underwriters Laboratories, Inc., Tests for Flammability of Plastic Materials for Parts in Devices and Appliances, 5th Edition
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes (2003)
EN ISO 14971	Medical devices – Application of risk management to medical devices (2000) (ISO 14971:2000) (Superseded standard: EN 1441)
ACR-NEMA DICOM version 3.0 - 2003	Digital Imaging and Communications in Medicine

5) Intended Use:

The intended uses of the MicroMaxx™ High-Resolution Ultrasound System (C3 Series) as defined by FDA guidance documents, are:

Ophthalmic	Trans-rectal
Fetal - OB/GYN	Trans-vaginal
Abdominal	Trans-urethral
Intra-operative (Abdominal organs and vascular)	Musculo-skel. (Conventional)
Intra-operative (Neuro.)	Musculo-skel. (Superficial)
Laparoscopic	Cardiac Adult
Pediatric	Cardiac Pediatric
Small Organ (breast, thyroid, testicles.)	Trans-esophageal (card.)
Neonatal Cephalic	Peripheral vessel
Adult Cephalic	

Typical examinations performed using the MicroMaxx™ High-Resolution Ultrasound System (C3 Series) are:

Abdominal Imaging Applications

This system transmits ultrasound energy into the abdomen of patients using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Cardiac Imaging Applications

This system transmits ultrasound energy into the thorax of patients using 2D, M Mode, color Doppler (Color), Tissue Harmonic Imaging (THI), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The heart, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size can be assessed for the presence or absence of pathology.

The patient's electrocardiogram (ECG) may be obtained and is used for accurate timing of diastolic and systolic function.

Warning: The ECG is not used to diagnose cardiac arrhythmias and is not designed for long term cardiac rhythm monitoring.

Gynecology and Infertility Imaging Applications

This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, M Mode, color power Doppler (CPD), color Doppler (Color), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The uterus, ovaries, adnexa, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally.

Interventional and Intraoperative Imaging Applications

This system transmits ultrasound energy into the various parts of the body using 2D, color Doppler (Color), color power Doppler (CPD), Tissue Harmonic Imaging (THI),and pulsed wave (PW) Doppler to obtain ultrasound images that provide guidance during interventional and intraoperative procedures. This system can be used to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, spinal nerve blocks and taps, ova harvesting, amniocentesis and other obstetrical procedures, and provide assistance during abdominal, breast, neurological surgery, and vascular intraoperative procedures.

Obstetrical Imaging Applications

This system transmits ultrasound energy into the pelvis of pregnant women using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The fetal anatomy, viability, estimated fetal weight, gestational age, amniotic fluid, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally. CPD and color Doppler (Color) imaging is intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

Warning: To prevent injury or misdiagnosis do not use this system for Percutaneous Umbilical Blood Sampling (PUBS) or *in vitro* Fertilization (IVF) The system has not been validated to be proven effective for these two uses.
CPD, or Color images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation (IUGR).

Pediatric and Neonatal Imaging Applications

This system transmits ultrasound energy into the pediatric patients using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The pediatric abdominal, pelvic and cardiac anatomy, pediatric hips, neonatal head, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Prostate Imaging Applications

This system transmits ultrasound energy into the prostate of an adult male using 2D, M Mode, color power Doppler (CPD), color Doppler (Color), and pulsed wave (PW) Doppler to obtain ultrasound images. The prostate gland can be assessed for the presence or absence of pathology.

Superficial Imaging Applications

This system transmits ultrasound energy into various parts of the body using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), and pulsed wave (PW) Doppler to obtain ultrasound images. The breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, and surrounding anatomical structures can be assessed for the presence or absence of pathology. This system can be used to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks and spinal nerve blocks and taps.

Transcranial Imaging Applications

This system transmits ultrasound energy into the cranium using 2D, color Doppler (Color), color power Doppler (CPD), and pulsed wave (PW) Doppler to obtain ultrasound images. The anatomical structures and vascular anatomy of the brain can be assessed for presence or absence of pathology. Imaging can be used temporally, trans-occipitally, or trans-orbitally.

Vascular Imaging Applications

This system transmits ultrasound energy into the various parts of the body using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), and pulsed wave (PW) Doppler to obtain ultrasound images. The carotid arteries, deep veins, and arteries in the arms and legs, superficial veins in the arms and legs, great vessels in the abdomen, and various small vessels feeding organs can be assessed for the presence or absence of pathology.

6) Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, CW Doppler, velocity color Doppler, Color Power Doppler, and duplex imaging) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA UD 3-2004) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

I_{SPTA} (d)	720 mW/cm^2	Maximum
Tis/TIb/TIc	0.0 – 4.0	Range
Mechanical Index (MI)	1.9	Maximum
I_{SPPA} (d)	0 - 700 W/cm^2	Range

The device's acoustic output limits for when used for ophthalmic applications are:

I_{SPTA} (d)	50 mW/cm^2	Maximum
TIs/TIb/TIc	0.0 – 1.0	Range
Mechanical Index (MI)	0.23	Maximum

The limits are the same as predicate Track 3 devices.